IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Liebel-Flarsheim Co.,	:	
	:	Case No. 1:01-cv-98-858
Plaintiff,	:	
	:	Judge Sandra S. Beckwith
vs.	:	
	:	
Medrad Inc.,	:	
	:	
Defendant.	:	

ORDER

Before the Court are multiple motions for summary or partial summary judgment. In this order, the Court will address the parties' motions concerning Plaintiff's "front-loading" patents, referred to throughout this order as the '669 and '261 patents. These motions are: Plaintiff's motion for infringement (Doc. 436); Plaintiff's motion that the patents are valid under 35 U.S.C. §112 (Doc. 437); Plaintiff's motion that the patents are valid over prior art (Doc. 450); and Defendant's motion that the patents are invalid under Section 112 and/or based on prior art references (Doc. 445). Each motion has been opposed and replied to. Defendant's motion for leave to file a sur-reply regarding these two patents (Doc. 481) is granted.

GENERAL BACKGROUND

This Court's prior orders, as well as the Federal Circuit decision[1] concerning the appeal from those orders, fully explain

[1] Liebel-Flarsheim v. Medrad, 358 F.3d 898 (Fed. Cir. 2004).

the products and patents at issue. Briefly summarized: Liebel-Flarsheim's '669 and '261 patents are part of a series of patents relating to powered injectors, products that can deliver contrast media into a patent's bloodstream for medical diagnostic procedures such as CT scans and angiograms. These two patents were derived from divisional applications that, in turn, were derived from L-F's original '110 application, filed on June 7, 1991. The '110 application, and L-F's '031 patent issued from it, are directed to front loading of syringes, an improved method over the older "breech loading" system then utilized in power injectors. The '669 application was filed on November 30, 1993 and issued October 5, 1995. The '261 amended divisional application was filed April 6, 1995 and issued August 19, 1997. As divisional applications, they share specifications and drawings. They also are presumed to have an effective date of June 7, 1991, the parent application's filing date.

When L-F filed its '110 application in 1991, all power injectors using disposable syringes used a pressure jacket, essentially a hollow tube that surrounds the syringe when installed in the injector. A pressure jacket, as generally described in the '669 and '261 patents, reinforces the syringe walls to withstand the rather high pressures created by the injection process. (See '669 patent, col. 7, lines 15-26; '261 patent, col. 7, lines 10-21). The patent specification unquestionably describes an injector with a pressure jacket. The abstract states in part that "the syringe is loadable and

unloadable into and from the injector through the open front end of a pressure jacket . . ." And L-F's originally filed application claims all explicitly reference a pressure jacket. (See Exhibit 8, Doc. 438, the complete File Wrapper for the '669 patent, at MED 002232-002278).

Medrad introduced a pressure **jacketless**, front-loading power injector at a trade show in November 1992. L-F later amended its '669 and '261 patent applications to eliminate most claim references to a pressure jacket. (See Exhibit 8, Doc. 438, at MED002309-002323). The critical '669 amendments were filed September 12, 1994 and the '261 amendment on April 6, 1995.

PROCEDURAL HISTORY

L-F's complaint, filed in 1998, alleges that Medrad's injectors and syringes infringe L-F's '669 and '261 patents. Medrad counterclaimed that the patents are invalid under several theories. After discovery and a claim construction hearing, the Court granted summary judgment to Medrad, finding that its products did not infringe L-F's asserted claims. The Court construed those claims to require a pressure jacket. Since it was undisputed that Medrad's products do not have a pressure jacket, the Court found the products did not infringe the patents. The Court also found Medrad's arguments concerning invalidity to be moot. (Doc. 247)

The Court addressed the parties' various arguments concerning L-F's "syringe sensing" patents (the '612 and '197 patents) in a separate order. (Doc. 271) The Court granted

summary judgment to Medrad, finding that its products did not infringe those patents.

The parties appealed these orders to the Federal Circuit, which reversed and remanded. See Liebel-Flarsheim Co. v. Medrad, 358 F.3d 898 (Fed. Cir. 2004). With respect to the '669 and '261 patents, the Federal Circuit held that the asserted claims do not require pressure jackets. The Circuit held in this regard:

> Moreover, even if the original disclosure supported Medrad's contention that the invention, as originally conceived, required the use of a pressure jacket, the prosecution history of the '669 and '261 patents makes clear that the patentee drafted the asserted claims specifically to cover injectors lacking pressure jackets. In light of the applicants' clearly stated intention to cover jacketless injectors, any question regarding the support or lack of support for the claims in the original disclosure bears on the issues of priority and validity, not on the issue of claim construction.

Id. at 902.

After remand to this Court, Medrad asserted that there were additional claim terms in the '669 and '261 patents that needed construction by this Court. After briefing the issue, this Court found that Medrad had waived any claim construction arguments not legitimately raised in Medrad's prior pleadings. (Doc. 423, 9/7/2004 Order) The Court also granted L-F's motion for partial summary judgment of validity of the patents based on inventorship and denied Medrad's cross-motion for invalidity on this issue. (Doc. 430, 10/20/2004 Order)

The parties have now submitted motions addressing infringement and invalidity of these patents, in light of the

Federal Circuit's mandate and this Court's prior orders.

Part I of this Order addresses the parties contentions on infringement. Part II addresses arguments concerning 35 U.S.C. §112. And Part III addresses prior art contentions.

ANALYSIS

I. Infringement.

L-F's Motion on infringement (Doc. 436) contends that Medrad's injectors (trade names MCT/MCT Plus, Envision CT, Vistron CT, Spectris MR, Spectris Solaris MR and Pulsar Ultrasound) and syringes (trade names 125-FLS, 125-FLS-Q, CTP-125-FLS, 200-FLS, 200-FLS-Q, CTP-200-FLS, SFD65, SFL65, SQK65, SSQK 65/115, UFL30, UDK50, and the Bracco prefilled 200 ml. syringe), literally infringe Claims 10, 11, 13, and 16-19 of the '669 patent, which describe a method of loading and unloading a front-load syringe to the power injector. L-F also seeks judgment for contributory and/or induced infringement of the same claims.

Claim 10 is representative of these asserted claims. It claims:

> 10. A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:
>
> providing a power injector having:
>
> a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,
>
> a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:

a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and

a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

('669 patent at Col. 15, lines 17-50, Exhibit 1 to Doc. 436)

The asserted claims of the '261 patent address a front loadable syringe (Claims 1, 9, 11-13 and 15-16) and a front loadable injector used in combination with a front loadable syringe (Claims 18, 22, 28, 30-32 and 34-37). Claim 30 is illustrative:

30. A front loadable injector for injecting liquid into an animal comprising:

an injector housing having a circular syringe receiving opening bounded by a circular annular periphery lying in a plane and syringe retaining structure spaced a fixed distance rearward of the periphery of the opening and positioned relative to the opening to be engagable therethrough;

> a plunger driving ram mounted in the housing and extendable along an axis through the opening;
>
> a syringe having a hollow body having a cylindrical tubular wall, a central longitudinal axis, a closed forward end having a discharge outlet therein, an open rearward end, a plunger snugly slidable within the hollow body in direct contact with the inside of the tubular wall and having a rearwardly facing drive engaging coupling thereon, and a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body;
>
> the ring of the syringe being monolithic with the tubular wall of the syringe and having a rearward facing planar annular surface dimensioned to overly [sic] the periphery of the opening; and
>
> the syringe having locking structure thereon monolithic with the tubular wall of the syringe and extending radially therefrom a distance smaller than the outward extension of said annular ring, spaced the fixed distance rearward of the ring and dimensioned to fit through the opening so as to engage the syringe retaining structure of the injector and urge the ring rearwardly to seal the syringe against the periphery of the circular opening on the injector to inhibit leakage of spilled fluid into the injector.

L-F contends that Medrad's accused products literally infringe L-F's claims because each claim element is present in Medrad's products. L-F argues that Medrad's own patent application (which matured into Medrad's '858 patent) clearly illustrates Medrad's intent concerning its product design, as well as its products' infringing nature. According to L-F, Medrad prepared and filed its '858 application without knowledge of L-F's then-pending '110 application. Thus the '858 claims give a "true reflection of Medrad's intent" concerning its power injectors and syringes. L-F's claim chart (Doc. 436, Exhibit 3) reviews each claim that L-F contends is infringed by Medrad's

products. And L-F's expert Dr. Guenther explains why the claim terms are infringed in his declaration (Doc. 436, Exhibit 6).

Generally, Medrad makes and sells "tubular replacement syringes" that operate at "high pressure." (This Court previously construed this term to mean injectors that operate in the range of 25 to 1200 psi; Medrad's Envision injector operates at 300 psi.) The accused injectors also have a "circular syringe receiving opening." The Federal Circuit found, contrary to this Court's previous conclusion, that the term "opening" or "syringe receiving opening" was not ambiguous, noting that in common usage an opening is simply an aperture. Since there was no ambiguity in the term, the Federal Circuit found no reason to read the term restrictively. L-F's motion points out that Medrad's injector has a "syringe receiving opening" as that term is commonly understood - e.g., the opening (or "aperture") that a syringe is put into.

Claim 10 also describes the syringe (that is placed into the "syringe receiving opening" of the injector), by the syringe being loaded into the injector by the syringe's rear end, and then rotated "a fraction of a turn" to "lock the [syringe] body" to the "rim" of the injector, which also engages the plunger on the syringe. Medrad's '858 patent, according to L-F, essentially describes the identical process, describing a "mounting assembly" with opposed retaining flanges rather than using the term "lock" or "locking the body of the syringe."

L-F concludes there is no material factual dispute, based

upon the plain meaning of its claim terms and the features of Medrad products, that L-F's patents are infringed.

Medrad's opposition (Doc. 456, Part IV, at pp. 55-84) notes that it is L-F, as the patent holder, who bears the burden of proving infringement by a preponderance of the evidence. An accused product must contain each and every limitation of the patent claim in order to literally infringe. See, e.g., Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998): "If even one limitation is missing or not met as claimed, there is no literal infringement." Medrad offers a number of arguments directed at various asserted claim terms, and says that its products do not contain those claim elements or limitations. Medrad also raises a "new" non-infringement argument, that L-F distinguished a prior art reference (the 1973 Runnells patent) during its prosecution of its '031 patent by stating that L-F's invention had a locking means at the front end of the syringe, an arrangement that Runnells did not disclose.

As noted above, this Court already ruled that Medrad waived any claim construction arguments that it had not fairly raised before. Medrad's opposition includes several non-infringement contentions that are based on claim terms that are raised for the first time. L-F therefore objects to all of these arguments.

Whether or not the argument about Runnells was "fairly raised" before, the Court can and will dispose of it. It is clear that the '031 patent claims an injector with a pressure jacket. The "front end locking means" described in that patent

is the means to lock the syringe to that pressure jacket. It is the law of **this** case, however, that the '669 and '261 patent claims do **not** require a pressure jacket. L-F's statements concerning the '031 patent claims and its "front end locking means" are irrelevant to the asserted '669 and '261 claims, and thus to the question of infringement of those claims. See, e.g., Biovail Corp. Int'l. v. Andrx Pharms., 239 F.3d 1297, 1301 (Fed. Cir. 2001): "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." (But see, Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004), where the common specification for three related patents "repeatedly and consistently" described the claimed inventions as communicating directly over a telephone line, and not over a packet-switched network like the internet, a conclusion supported by the applicant's prosecution history statements. Despite the fact that the claims were not limited to a telephone line system, the Court held the patent covered only telephone line communications: "Multi-Tech's statement to the PTO was thus not limited to the invention disclosed in the '627 patent, but was a representation of its own understanding of the inventions disclosed in all three patents.")

L-F has also moved to strike all of Medrad's claim arguments and evidence. (Doc. 479) Medrad insists that the Court cannot

meaningfully rule on infringement unless the claim terms are fully understood and construed as needed. Medrad pleads it is not seeking construction of any ambiguity in any claim term, but is only arguing non-infringement based on ordinary meaning or by using L-F's own chosen meaning. Medrad raises the specter of a second reversal by the Federal Circuit if the Court's infringement decision is not based on a "full" explanation of the Court's findings concerning claim terminology. See, e.g., Nazomi Communications v. ARM Holdings, 403 F.3d 1364, 1371 (Fed. Cir. 2005), vacating a judgment of noninfringement and remanding for detailed findings on both claim construction and infringement analysis. There, the Federal Circuit noted that, while it "rarely remands the issue of claim construction," it found the district court's analysis inadequate to permit meaningful appellate review of the infringement determinations. See also, Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 791 (Fed. Cir. 1995), reversing infringement judgment and remanding for detailed claim construction rulings.

A few of Medrad's current arguments were at least mentioned in prior pleadings; for example, arguments concerning the claim terms "open rearward end" and "locking structure" were raised in Medrad's 4/5/2001 opposition to L-F's motion for partial summary judgment (Doc. 176). Medrad defends the balance of its current claim/infringement arguments because they were "timely" raised in its final supplemental discovery responses. Medrad overlooks the fact that these responses were served in October 2004 - **after**

this Court ruled that Medrad had waived further claim construction on these patents.

The Court's prior order precluding Medrad from raising new ambiguity arguments was premised upon Medrad's conscious waiver of additional claim construction arguments based upon Medrad's assertions of ambiguity of L-F's claims. The Court was not, and is not, inclined to permit piecemeal litigation of these issues, which would have required another Markman hearing, and would have created additional costs and delays. The Court's order was **not** tantamount to directing a judgment of infringement, as Medrad suggests. Medrad may argue non-infringement, and oppose L-F's infringement contentions, based upon unambiguous terms used in the claims. L-F's original infringement motion (Doc. 169 at p. 22) states the obvious fact that "for those claim terms over which there is no dispute, the Court need only apply the common, ordinary meaning."

The Court is also mindful that this case is now seven years old. Given the Court's significant investment in studying the parties' patents, products and positions, and given the probable appeal of any final judgment in this case, the Court finds that efficiency is best served by addressing Medrad's claim arguments in deciding infringement, based upon common meaning or upon L-F's own position concerning the meaning of a claim term.

The '669 Claims

1. "Pressure Cap." Medrad says that the '669 and '261 patents describe a syringe that includes a "pressure cap" located

at the front (forward) end of the syringe. See, e.g., '669 patent col. 7, lines 49-51. Medrad's syringes do not have such a "pressure cap." Medrad's argument ignores the language of independent claims 10 and 19, which do not include a "pressure cap" limitation, and which the Federal Circuit has instructed cannot be limited by importing terms mentioned in the specification. See, Liebel-Flarsheim v. Medrad, 358 F.3d at 904-905; see also, Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005 en banc):

> Moreover, we recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998) ("there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification"). However, the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the **claim terms**. (emphasis added)

The lack of a "pressure cap" is not tantamount to a finding of non-infringement of the claims.

2. "Programmed Speed." Medrad argues its injectors require the operator to input a desired "flow rate" for the media in the syringe. This, says Medrad, is different from L-F's claim of a "programmed speed" used in Claim 10. Medrad doesn't dispute that its injector is "programmed" (e.g., provided with computerized control circuitry) to translate the desired flow rate (volume of fluid delivered per defined time period) into a

command to move the plunger. The correct speed must obviously be used in order to deliver the desired "flow rate." The entire phrase from the patent makes L-F's claim plain: moving the plunger ". . .at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate . . ." Medrad's injectors unquestionably utilize and operate at a "programmed speed."

3. Do Medrad's Syringes Have a "Rim"? The '669 claims require the syringe to have a "generally circular rim" which is "locked around the periphery of the [injector] opening." Medrad rhetorically posits three different parts of its syringe that "might" qualify as a rim, and offers reasons why none of them do. Again, it is the **claim** language that is most relevant, not L-F's specification or its '031 patent prosecution. Claim 10 states that the syringe includes a "cylindrical body" and "a generally circular rim." A "rim" is commonly and generally understood to be an edge or an outer boundary, like the rim of a glass or a basketball hoop. Medrad's syringes are undeniably "cylindrical" and have a "rim" which is the end or outer boundary of the cylinder, which is "generally circular." The presence of the flanges on Medrad's syringes does not change the "generally circular" nature of the syringe's rim, nor make the "rim" something other than an edge or outer boundary.

4. "Around" the "Periphery" of the Injector. Medrad next argues its syringes do not lock "around" the "periphery of the opening" of the injector. Medrad relies on Fig. 5 of the

patent drawings to try to import a limitation into the claim, which once again the Court cannot accept. There is no doubt that Medrad's syringes are placed into the opening of Medrad's injector, and turned (rotated) to engage the flanges with the slots. The syringe is thus "locked" by the rim "around" the opening on the injector. Nothing more is required.

5. "Generally Circular Periphery." Medrad admits (as it must) that its injectors have openings (an "aperture") but argues that the openings are not "generally circular." The Medrad injector openings have "slots" to accommodate the flanges on the syringes. (See graphic on p. 75 of Doc. 456.) As with the "general circular rim" on Medrad's syringes, the presence of the slots does not transform what Medrad itself describes as "essentially cylindrical" openings on its injectors, into openings that are not "generally circular." The photograph of the Envision CT injector head (Doc. 436, pp. 16 and 26), as a picture so often does, says far more than Medrad's words, and clearly establishes the "generally circular periphery" on the injector opening.

6. No "Open Rearward End." Claim 19 of the '669 patent, and various of the '261 claims, describe a syringe with an "open rearward end" which Medrad contends its syringes lack. Claim 19 is directed to a method of "removing" a syringe, and recites that the injector receives the back end of the syringe, ". . . such that the ram is extendable into an open rearward end of a syringe inserted in the opening." Once again, Medrad points to the

specification describing a "syringe" as including both a "case" and a "plunger." Because Claim 19 does not say "syringe case" with an open rearward end, Medrad says the claim cannot be construed to mean a syringe with a plunger at the rearward end. And since all of Medrad's syringes have plungers at the rearward end, they do not infringe.

Once again, the specification language Medrad cites does not limit the language of Claim 19, which simply uses the common word "syringe" which Webster's 9th College Dictionary defines as "a device used to inject fluids into or withdraw them from something" including an instrument "that consists of a hollow barrel fitted with a plunger and a hollow needle." Moreover, it is not at all clear that the language Medrad relies on (see Col. 7, lines 49-54) specifically limits the meaning of "syringe" as Medrad suggests. The specification also describes an "open proximate end" of the syringe (Col. 7, line 53), which is fully consistent with the language of Claim 19. Medrad's syringes are "open" enough at the rearward end that they can be installed on the injector. Nothing more is required.

7. "Locking" and "Unlocking" the Syringe. Medrad notes that the specification (Col. 13, lines 21-25) describes the "locking structure" as between the syringe front end and the pressure jacket. Since Medrad's injectors don't use pressure jackets, Medrad suggests that its injectors do not have a "locking structure." The Court finds that this argument is foreclosed by the Federal Circuit's holding that the claims are

not limited to an injector with a pressure jacket. The Federal Circuit specifically rejected this Court's prior conclusion that the claim term "syringe receiving opening", and similar language used in other claims, was ambiguous concerning where the opening had to be, and this Court's reliance on the specification's recitation of the "opening" being on the front end of a pressure jacket. (See 358 F.3d at 904-905) The Court must conclude that the "locking structure" described in the claims need not be solely between the syringe front end and a pressure jacket.

Medrad then argues that the common meaning of "locking" is a fastening operated with a key, or a fastener that cannot be easily or simply disengaged. There is nothing anywhere in the patent giving rise to a suggestion that "locking" is used in this sense. Rather, all references to "lock" and "unlock" refer to the "fastening" of the syringe to the injector in a secure fashion, so that it will not dislodge during injector operation. Indeed, the Oxford English Dictionary's first definition of lock is simply "[a] contrivance for fastening." Medrad's products clearly include a "contrivance for fastening" the syringe to the injector, as the syringe is rotated to "lock" onto the injector by engaging the flanges to the "slots" in the injector head.

8. "Threaded" Syringes. Claim 13 of the '669 patent, which is dependent on Claim 10, describes the locking of the syringe to include "the step of **threading** the rim [of the syringe] around the opening [of the injector]" (emphasis added). Claim 10 describes this step as "rotating the syringe in the

opening a fraction of a turn to thereby lock the body round the rim to the injector around the periphery of the opening." Medrad argues its syringes lack "threads," as that term is commonly understood, and therefore cannot be "threaded" around the injector's opening. Medrad does not state what the common understanding of "threaded" may be, but says that its syringe attaches with a bayonet connection, not a "thread." (The Court notes that Medrad's '858 patent uses the term "retaining flanges" to describe the mating of the syringe and injector. See '858 patent, Col. 4, lines 21-33.)

"Threads" are referred to several times in L-F's '669 specification. For example Fig. 3, item 66 is described as an "external thread" on the end of the syringe case that mates with "threads" on the interior of the tubing collar (Col. 8, line 1). See also Fig. 5, items 85 and 86, described as "threads" on the syringe cap and the pressure jacket (Col. 8, lines 47-65). These "threads" tighten and secure the syringe to the jacket when the syringe is rotated 45 degrees. The screws that hold the pressure jacket to the injector are also described as "threaded" into holes in the injector door. (See Col. 7, lines 45-47) L-F relies on the patent's description of the alternate embodiment shown in Fig. 15, describing the locking structure to "include external threads 200 formed of four equally spaced, radially outwardly directed thread sections (flanges), each spanning slightly less than 45° about syringe body 257, which mate with internal threads 201 formed of four equally spaced, radially

inwardly directed mating thread sections (flanges) . . .” (‘261 patent, col. 13, lines 23-29) Thus L-F asserts that “threads” and “flanges” as used in Claim 13 are essentially interchangeable. L-F also notes that Medrad makes no argument about the ‘261 patent term “threads”.

The Oxford English Dictionary defines “threaded” as “interlaced, twined,” or “[h]aving or furnished with a screw-thread.” It defines **thread** (see Definition 5) as “[t]he spiral ridge winding round the shank of a screw; also, each complete turn of this; a similar ridge round the inside of a cylindrical hole, as in a nut or a screwhole.” A “flange” is defined in part as “[a] projecting flat rim, collar, or rib, used to strengthen an object, to guide it, to keep it in place, to facilitate its attachment to another object, or for other purposes.” The two terms can have slightly different technical meanings when thread is used to refer to a “screwthread.” But L-F’s alternate embodiment description plainly states that L-F intended a “thread” to be the same as a “flange.” The Court concludes that the lack of a “screwthread” on Medrad’s syringes does not amount to a conclusion that they do not infringe Claim 13.

9. “Retracting the Ram.” Dependent Claim 18 describes the step of “after engaging the plunger with the ram and before the step of energizing the motor and thereby driving the ram forward, retracting the ram and thereby rearwardly moving the plunger . . . .” Medrad notes that its empty syringes are **always** attached to the injector (thereby “engaging the plunger with the

ram") with the ram retracted. Thus, Medrad's injectors do not meet the claimed step of retracting the ram after engaging the plunger and before driving the ram forward. L-F responds that Claim 18 simply says that ram retraction must happen before any fluid can be injected. While that is true, Claim 18 claims a specific temporal relationship between engaging the plunger and retracting the ram. Medrad's injectors do not and cannot operate in the fashion described in claim 18, and do not infringe this dependent claim.

The '261 Claims

Medrad raises several arguments about the '261 claim terms, which are essentially the same as the '669 arguments (see pp. 80-84, Doc. 456). For the same reasons discussed above, the Court rejects Medrad's arguments that its products do not infringe the '261 asserted claims.

Medrad also argues that during prosecution of its '261 patent, L-F adopted the claim term "locking structure" to describe the connection between the syringe and the pressure jacket, in response to PTO objections that the specification did not support the claims. This, says Medrad, is an admission that the "locking structure" described in the claims must include a pressure jacket limitation, and not merely a "locking structure" somewhere else on the injector. Once again, the Court finds that Medrad's argument is precluded by the Federal Circuit's decision. The Circuit specifically cited L-F's prosecution statement about its amended claim, that "the locking structure is not necessarily

at the front end of the syringe, nor is there necessarily a pressure jacket" to conclude that the claims do not require a pressure jacket. This Court is constrained to reach the same conclusion about the term "locking structure" as used in the '261 claims.

After reviewing all of Medrad's arguments concerning all disputed claim terms, the Court finds that each and every limitation of the asserted claims of the '669 and '261 patents - with the exception of dependent claim 18 of the '669 patent - are present in Medrad's accused products. Therefore, the Court grants L-F's motion and finds that Medrad's accused injectors and syringes infringe the asserted claims of L-F's '669 and '261 patents.

II. Invalidity of the Patents Under 35 U.S.C. §112.

Both parties have moved for summary judgment on the question of the validity or invalidity of the patents under 35 U.S.C. §112. Medrad originally sought judgment on this basis in 2000 (Doc. 57), a motion the Court found to be moot due to the Court's prior decision on non-infringement of these patents. The Federal Circuit specifically directed that the questions of validity and priority must be separately addressed on remand.

Medrad's motion seeks judgment based on Section 112's "written description" requirement (Doc. 445, p. 3 n. 1), but its opposition to L-F's own motion on validity (Doc. 456) argues both the statutory written description and enablement requirements. L-F's motion addresses both (Doc. 437).

The Patent Act, 35 U.S.C. §112, requires the patentee to provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc., 418 F.3d 1326, 1336 (Fed. Cir. 2005). See also, Crown Operations Int'l v. Solutia Inc., 289 F.3d 1367, 1378-79 (Fed. Cir. 2002), noting that a patent specification may "enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement" (internal quotation and citation omitted).

An adequate description is required "to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000). As for enablement, the specification "must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation." Warner-Lambert, supra, 418 F.3d at 1337 (citations omitted). "The key word is 'undue,' not experimentation." Id., quoting In re Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988). When a specification is challenged under Section 112, clear and convincing evidence is required to overcome the presumption of validity that attaches to every patent.

The Federal Circuit has also stated that the applicant must

"convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. . . . One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Lockwood v. American Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997), quoting from Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). This is equally true when measuring the specification against a patentee's later amended claims. "The fundamental inquiry is whether the material added by amendment was inherently contained in the original application." Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000).

The Court concludes that the specification of the '669 and '261 patents fails to meet this test. The specification does not describe a powered injector without a pressure jacket. No where in the specification is there anything that describes an injector without a jacket: no words, no structures, no figures, and no diagrams. The abstract clearly describes an injector that allows the easy loading and unloading of a syringe through the open front end of the pressure jacket. Every relevant drawing presumes the presence of the pressure jacket. The background to the invention recites the fact that pressure jackets are used due to the impracticality of using disposable syringes in a power injector (as they cannot withstand the injector pressures). The rest of the specification presumes the use of the pressure jacket, and the invention is directed to improvement of loading

and unloading the syringe given the constraints presented by the pressure jacket. The summary of the invention clearly and consistently refers to "the" pressure jacket (as opposed to "a" jacket) indicating its constant, presumably fixed presence on the injector. (See col. 2, lines 36, 38, 47-48, 50, 55, 67; col. 3, lines 1, 7, 9, 145, 17, 20-21, 22, 23, 28). The same is true with respect to the summary description of the preferred embodiment (Col. 3, lines 29-52). In fact, the Court cannot find one reference to the pressure jacket that does **not** use the specific "the" in its description. The Oxford English Dictionary defines "the" when used as a definite article or demonstrative pronoun, as "[m]arking an object as before mentioned or already known, or contextually particularized (e.g. 'We keep a dog. We are all fond of *the* dog')." Clearly, L-F "contextually particularized" its pressure jacket description by making it part and parcel of its described invention.

The Court's conclusion on description is buttressed by an examination of the enablement requirement. In re Wands, supra, set out factors useful in determining the "undue experimentation" question. Those factors are: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

(1) Quantity of experimentation: The several critical

functions served by the pressure jacket are relevant to this inquiry. The jacket maintains the integrity of the syringe housing against pressures the syringe encounters during operation of the injector. According to the named inventors on the '669 and '261 patents, Frank Fago and Paul Dieterlen, the pressure jacket also serves as a guiding mechanism; it centers the syringe during loading in order to avoid contact between the syringe walls and the ram. (Fago Depo. at 123, Dieterlen Depo. at 131-32, Goethel Depo. at 488). This is important to maintain syringe sterility. Therefore, to make a jacketless injector system, one would have to account for the pressure retaining **and** guiding characteristics of the pressure jacket. And the pressure jacket as described provides the mechanism for attaching the syringe securely to the injector. Thus, the jacket not only assures the structural integrity of the syringe housing itself, but also the integrity of the attachment of the syringe to the injector. Medrad's expert Solar describes similar functions and design issues for the pressure jacket. (Medrad's Exhibit 24, Solar Declaration, ¶11-12)

L-F's own unsuccessful experimentation and testing to try to produce a jacketless system are also illustrative. In a Dec. 4, 1992 memo regarding "Medrad Front Load Injector," Frank Fago reported that L-F's testing of a jacketless device indicated it was "too risky at 300 psi due to syringe ballooning and the

possibility of blow by."[2] (Medrad's Exhibit 9, Sturges Declaration, Exhibit 12 to Sturges) Mr. Fago concluded that a problem still existed at 200 psi. (Id.). Mr. Fago wrote this memo more than one year **after** L-F filed the original patent application. He testified that an unknown amount of testing would be required to create a jacketless injector system. As he candidly stated, "When you go down the road of a design like that there are always other problems that you would find, unknown problems, I guess you could say, because it's new." (Fago Depo. pp. 84-85; Sturges Decl. Exhibit 9) He also testified:

> Q. But to get a syringe that could be used without a pressure jacket that would be used with patients, you would had to have gone a lot further in the design process than you did; is that correct?
>
> A. Yes.
>
> Q. So essentially you did some discussions, you did some testing, you did some calculations, but there was a lot more you would had to have done to get that to become a product?
>
> A. Before we had that as a product, yeah, there would be a lot more to go.
>
> Q. And you would have to have done a lot to determine that you could get a product to work; is that correct?
>
> A. That would be an issue that would have to really be looked at by a number of people that would have to determine what the specification is and what the concessions all would have to be to do that.
>
> Q. And [L-F] didn't do that, though, did they?
>
> A. I was not involved with that.

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[2] Fago described "blow by" as a syringe failure mode, when the fluid in the syringe "goes past the plunger." (Fago Depo. p. 28; Doc. 168, Exhibit 8).

Q. But did [L-F] do that at some point?

A. I was not involved in any discussion where we did that.

Q. And you're not aware of any?

A. I'm not aware of any.

(Fago Depo. at 95-96).

Mr. Dieterlen also testified about the memo mentioning a "Quick connect syringe with no pressure sleeve" as a potential design option. He was not aware of any testing other than that described by Mr. Fago:

Q: Why do you think [L-F] decided to stay with the pressure sleeve design at that time?

A: I assume that maybe it was a quicker way to market than having to deal with the unknowns of developing a new syringe. I think that's a lengthy process to work out all the bugs in a new syringe, because there are always molding problems that have to be worked out. And the first trial, you know, would be likely to need changes, so I think it might take a few iterations to get to the point where you would have a good design. And it would be expensive and time consuming. I guess maybe they felt like the benefits to be gained didn't justify that work for the product that they had in mind.

(Dieterlen Depo at 130-131; Sturges Declaration Exhibit 6) Mr. Goethel confirmed that tests conducted on a syringe without a pressure jacket indicated that the syringe would not withstand the pressure applied to it, rendering the test unsuccessful. (Goethel Depo. at 136).

Despite this evidence, L-F argues that a pressure jacket is merely "a design option" that L-F elected and Medrad did not. L-F points to the fact that Medrad's own '858 patent also describes injectors "with or without" pressure jackets. While it may well be a "design option," L-F's own engineers confirm that it was not

an available or even imagined "option," in the sense that it could have been simply exchanged (by one skilled in the art) for another "option" capable of fully performing its functions. L-F suggests that eliminating the pressure jacket is a simple plus/minus economics decision concerning choice of syringe material and manufacturing molding techniques. But it seems painfully obvious that adding a pressure jacket to a fully specified jacketless injector is a far different process than removing the jacket from a jacketed injector like the one described in L-F's specification. Where and how would the syringe attach to L-F's injector if the jacket were simply omitted, as L-F suggests? The "locking mechanism" used to secure the syringe to the injector is implicated when the pressure jacket is eliminated. L-F recognized this in its Dec. 20, 1989 minutes of a "brainstorming" session on syringe design (Sturges Declaration Exhibit 27): "Also, to coincide with the elimination of the pressure sleeve, some feature would be provided on the syringe to allow easy installation and removal from the injector." That undescribed, unspecified "feature" would be an essential part of the invention of a jacketless injector, as it must cope with both how the syringe attaches and how the attachment withstands the pressure exerted by the injector.

(2) The amount of guidance or direction presented: This Wands factor permits the Court to consider the patent's guidance or direction in making the invention. L-F's original patent application did not even suggest the concept of removing or

eliminating the pressure jacket, nor did L-F offer a drawing or description of an injection system for a disposable syringe that does not use a pressure jacket. (Doc. 438, Exhibit 8, complete '669 file wrapper) Rather, the specification describes "the present invention" as an improvement for loading and unloading syringes from the pressure jacketed injector. (Id. at pp. MED001802-001805) Mr. Goethel reviewed the application and, like this Court, could not find a description of an injector for use with a disposable syringe that did not use a pressure jacket. (Goethel Depo. at 468; Medrad's Exhibit 12). L-F's later amended and supplemented claims that eventually became the patent claims at issue here dropped references to a pressure jacket, in view of (Medrad contends) the market introduction of Medrad's jacketless injector. There is nothing nefarious nor unfair about broadening claims to encompass a competitor's marketed product. See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988): "Nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant." But, the amendment must be supported by the original application.

In PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235 (Fed. Cir. 2002), the Federal Circuit agreed that a claim that had been amended after its original application was invalid because it was

not supported by the specification. There, the invention dealt with a process to chemically inhibit the growth of sprouts on potatoes (and other tubers). The application described a composition of two chemicals being applied, but the amended claim described a stepped application of one, followed by the other. The patentee argued that the specification clearly encompassed a sequential application, but the Court disagreed, finding that the new claim was directed to a new subject matter, and "that no reasonable juror could conclude otherwise." Id. at 1248. The Court arrives at the same conclusion concerning L-F's patents in issue here.

(3) Working examples: Mr. Goethel did not recall any prototypes L-F ever made of a pressure jacketless CT injector or syringe. (Goethel Depo. at 88, 486). L-F does not argue that it ever made a prototype. L-F simply argues that this fact is irrelevant. In re Wands, supra, suggests otherwise.

(4) State of the Art: All evidence indicates that, in 1991, the state of the art was such that a jacketless system would have been a true innovation. All of the named inventors of the asserted patents admitted that, to the best of their knowledge, in 1991, a CT injector that used a disposable syringe and did not have a pressure jacket would have been a new concept. (Goethel Depo. at 465; Fago Depo. at 187; Dieterlen Depo. at 141; Neer Depo. at 135). They also agreed that as of 1991, nobody had introduced a CT injector using disposable syringes that did not have a pressure jacket. (See Goethel Depo. at 466; Fago Depo. at

103, 187; Dieterlen Depo. at 141; Neer Depo. at 135).

L-F argues that during development of its front loadable system it considered design alternatives that did not include a pressure jacket. In a March 1988 document, Mr. Goethel notes that "[c]onsideration should be given to eliminating the pressure jacket as we know it or at least reducing its structural capacity ... ." (Sturges Declaration, Exhibit 21) Notes dated 12/14/88 state that it "[m]ight even be possible to eliminate the pressure jacket." (Sturges Declaration, Exhibit 23) Notes from December of 1989 suggest consideration of a thinner pressure sleeve, a special pressure jacket, or no pressure sleeve at all. (Sturges Declaration, Exhibit 26). And the 12/20/89 memo quoted above (Sturges Declaration, Exhibit 27) includes the design idea of eliminating the pressure sleeve by making the syringe stronger. An action item included in that memorandum was to "[t]est 260 ml syringe without pressure jacket to see how much pressure it can take and determine it's [*sic*] pressure to expansion ratio." (Id.) Syringe design notes dated 3/8/90 again list possible improvements over current designs as reducing pressure sleeve wall thickness, eliminating the pressure sleeve, a quick connect syringe with no pressure sleeve, or designing the syringe/pressure sleeve system to allow frontal loading of syringe. (Sturges Declaration Exhibit 28)

Many years later in this litigation, however, Mr. Fago testified that L-F could have developed a working, jacketless device merely through concessions on syringe material cost or

maximum pressure capacities. (Fago Depo. at 186). The record evidence belies his assertion.

Medrad also argues that L-F's positions taken during the re-examination of Medrad's own '858 patent confirm that the specification does not describe a jacketless invention. During the '858 reexamination, as noted, L-F pointed to the pressure-jacketed embodiment in its '031 patent, emphasizing the mating mechanism on the forward end. Claim 7 and 8 of the '858 patent withstood L-F's challenge, as they claim a jacketless, rear-attaching system. The PTO specifically found that L-F's '031 patent did not teach a syringe-injector connecting invention ". . . wherein the retaining flange and sealing flange **cooperate for mounting the syringe on the injector housing with an interference fit**" (emphasis added). See Exhibit 129, Doc. 456. The Court believes that Medrad is correct when it argues that the PTO would have also rejected Medrad's Claims 7 and 8 of the '858 patent that claim a jacketless, rear-attaching syringe if the PTO believed that L-F's specification encompassed the same invention.

To accept L-F's argument that its description is adequate, one would have to accept the premise that a jacketless power injector is nothing but a "different embodiment" of the specified invention. The Court is unable to accept that premise. An "embodiment" is defined by OED as "[t]hat in which (a principle, an abstract idea, etc.) is embodied, **actualized, or concretely expressed**." A jacketless injector is neither actualized nor concretely expressed in the patent. (Similarly, "mode" is

defined as "any of a number of distinct ways of operating a device or system." Any "mode" to make the injector specified by L-F, best or not, would have to include a pressure jacket as part of the specified device or system.) It cannot simply be a "different embodiment" of L-F's specified invention (ease of loading, front loading of a syringe through the jacket) to completely eliminate the pressure jacket, change the attachment point of the syringe, provide for the needed strength of that new attachment point, AND provide for additional strength in the syringe casing itself. To accept that argument is, in the Court's view, contrary to the Federal Circuit's holdings in PIN/NIP, Inc., supra, and in AK Steel Corp. v. Sollac, 344 F.3d 1234 (Fed. Cir. 2003), where the Circuit affirmed summary judgment of invalidity under Section 112. In AK Steel, the patentee's original specification made clear that their invention (a coating for stainless steel) did not "work well unless the aluminum [used in the coating process] is substantially pure." The patentee's continuation application based on the same patent, however, had broader claims that the coating metal be "aluminum or aluminum alloys" or simply have enhanced wetting characteristics (improving the quality of the coating process). The Circuit found that the patentee's expressions in the specification about the pureness of the aluminum was not just a theory, but rather it spoke directly "to the conditions under which the invention will or will not operate properly." Id. at 1240. The Court reaches the same conclusions about the role and

necessity of the pressure jacket in L-F's specification.

Medrad has proferred clear and convincing evidence that the specification does not satisfy 35 U.S.C. §112's dual requirements of a written description and enablement of a jacketless power injector. The Court therefore concludes that the asserted claims of the '669 and the '261 patents are invalid under 35 U.S.C. §112. As Medrad cannot infringe an invalid patent, the Court grants Medrad's Motion for Summary Judgment on this question (Doc. 445) and denies L-F's Motion (Doc. 437).

III. Invalidity of the Front-Load Patents Based on Prior Art.

The parties have also sought summary judgment that the '669 and '261 patents are valid (L-F's motion, Doc. 437) or invalid (Medrad's motion, Doc. 445), based on anticipation and/or obviousness in prior art. Related arguments are contained in the parties' opposition briefs to the motions; see Doc. 456, Medrad's opposition to L-F's motion, and Doc. 465, L-F's opposition to Medrad's motion. While the Court could find this issue moot due to the invalidity ruling in Section II infra, the Court will address the parties' motions on this subject in the alternative, given the likely appeal and in the hopes of moving this case ever closer to a final resolution.

Initially, the Court notes that L-F has moved to strike the "working models" constructed by Dr. Sturges of various prior art patents, described in paragraph 45 of his declaration concerning the front-load patents (Doc. 445, Exhibit 9). L-F objects to the models on various grounds, including that the models do not

faithfully or fairly depict the patented inventions. The Court need not and will not resolve this dispute at this time. In the face of L-F's objections, the Court has not reviewed the models (submitted on a CD as Exhibit 90 to Medrad's motion) for purposes of ruling on the parties' motions. The motion to strike is denied, without prejudice to renewal in the event the issue becomes relevant to some future dispute.

Medrad and its experts argue that asserted claims 10, 13, 16 and 17 of the '669 patent are anticipated and/or made obvious by various references, either alone or in combination with others. See Doc. 445, Exhibit 9, Sturges Declaration, and Exhibit 24, Solar Declaration.[3] Invalidity based on anticipation requires Medrad to prove that a single prior art reference has "all of the elements contained in the claims limitations." See Crown Operations Int'l v. Krone, 289 F.3d 1367, 1375 (Fed. Cir. 2002). The obviousness test hinges on four factual findings: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." Nat'l Steel Car, Ltd., v. Can. Pac. Ry., Ltd., 357 F.3d 1319, 1334 (Fed. Cir. 2004).

The Glass '547 patent discloses an injector used with a pre-filled vial (or ampule) that gives no indication that it can

[3] For ease of reference, the Court will refer only to the Sturges Declaration in this discussion, as the Solar and Beck declarations are largely identical to Dr. Sturges.

withstand the "high pressures" disclosed in L-F's patents. Sturges concludes that the Glass device "could operate" at a pressure of 100 psi (Sturges ¶46) but does not explain where that conclusion finds support in the language of the Glass patent. (The patent expressly describes the "cartridge" as made of **glass** or other "suitable material" (see col. 3, lines 52-54) but says nothing about pressure requirements.) As that is a critical feature of the asserted claims, that alone is enough to find a lack of anticipation. But in addition, the Glass patent has no "engagement" between the injector's piston and the "plug" in the ampule. The asserted claims all describe the step of "engaging" the injector ram to the syringe plunger, an element missing from Glass. Sturges suggests that Glass combined with the Kranys '736 and the Reilly '980 inventions would make the engagement "an obvious modification" to Glass. (Sturges ¶47) Both Kranys and Reilly describe a "turret" mechanism to which the syringe is loaded and it is this "turret," not the syringe, which is actually rotated. Reilly also explicitly describes the **ram** being rotated in order to disconnect it from the syringe. Sturges' own conclusion of "obviousness" is not clear and convincing evidence that is required to establish obviousness based on a combination of these three patents.

The Campkin '480 patent, issued in 1932, describes a hypodermic syringe that can be driven by a motor, the syringe being made of glass. The patent describes the syringe (or vial) being held by a flange at the forward end of a "holder" thus

requiring the vial to be loaded from the rear. Sturges asserts that this patent discloses "front-loading a syringe onto an injector for injecting fluid at high pressure" but utterly fails to tie his conclusion to specific language in the Campkin patent and its claims. The Court will not accept this conclusion in the absence of any language in the patent supporting it. Moreover, as with the Glass patent, Sturges asserts that it is "obvious" that the Campkin device is capable of withstanding 100 psi pressure, but the patent simply does not support that conclusion. The only reference to pressure the Court can find concerns "dental pressures" (col. 2, lines 7-9) which are not further described and which Sturges does not address, nor explain how they are relevant to angiographic or CT pressures addressed in the L-F patents.

The Michel '439 patent (Exhibit 49 to Sturges Declaration), issued in 1986, discloses a "Portable Infusion Unit." The injection ampule slides into a casing, the ampule being held in place by a "connecting part 27" at the forward end of the ampule. The connecting part must be screwed into the casing, and must be unscrewed and removed before the ampule can be removed. Despite this description, Sturges asserts (at ¶50) that the ampule (or "syringe") can be removed by "forward axial movement with the catheter tubing connected to the outlet orifice of the syringe." The patent language fails to support Sturges' assertion in this regard. As with the patents discussed above, Sturges fails to support his naked conclusion that Michel discloses a device "that

could operate at a pressure of 100 psi." Medrad has failed to proffer clear and convincing evidence that the Michel '439 patent contains each element of L-F's patents.

The Stolzenberg '417 patent (Exhibit 45 to Sturges Declaration), issued in 1971, describes an "Osmotic Fluid Reservoir for Osmotically Activated Long-term Continuous Injector Device." The title alone discloses the obvious distinction, that Stolzenberg describes an injector controlled by varying osmotic pressures, not by a motor. Moreover, the "fluid reservoir" (which Sturges analogizes to a "syringe") contains a "freely movable piston" that moves by osmotic pressure created by migrating solvents. There is no ram that moves any part of the injector. Rather, the inventor describes as a "piston" the movable piece within the reservoir (akin to a "plunger" in a syringe) which moves only in response to osmotic pressure differentials.

Sturges tries to cure this rather glaring distinction by arguing that Stolzenberg could be combined with the Reilly '980 patent (describing a powered medical injector with a powered ram), as it would be an "obvious design choice" to substitute osmotic pressures (used in the Stolzenberg implantable device) with a motor-driven ram. While he concludes that this is "obvious," Sturges utterly fails to explain the basis for his conclusion that two such different technologies could be "combined" so easily and obviously, much less why or how this would be "obvious" to one skilled in the art.

The Wootten '843 and '138 patents (Exhibits 46 and 47 to Sturges Declaration) disclose a method and device for the injection of vascular contrast media. They describe an injector which can deliver contrast fluid at variable rates. Sturges argues that the Wootten patents contains all elements of claim 19 of the '669 patent. (Sturges ¶52) The '843 patent describes a "syringe hold-on nut 32 having threaded engagement with the OD of the syringe housing 29 releasably retains the syringe barrel 30 within the syringe housing 29 . . . ." See Col. 4, lines 13-16. But L-F persuasively points out that Wootten describes a multi-step process for dismantling and re-assembling the syringe, in order to sterilize all its parts and then refill it for re-use. See, e.g., Col. 6, lines 38-65; Col. 8, lines 27-36. This does not anticipate the step of Claim 19, of "unlocking the syringe from the injector and removing the syringe from the opening by forward axial movement thereof with the tube connected to the orifice of the syringe."

Medrad also offers several arguments concerning L-F's '261 patent, based largely on the same prior art references discussed above. The Court will briefly discuss each one below.

The Stolzenberger '417 patent describes the implantable osmotic-pressure controlled infusion device. Sturges asserts that "each and every element" of each asserted '261 claim is disclosed in Stolzenberg, or is obvious when combined with Reilly '980 or Heilman '474. (Sturges ¶54) As noted above, the Stolzenberg invention is substantially different from a powered

medical injector, and the patent does not contain the elements of the '261 claims - e.g., "a planar annular ring surrounding and extending outwardly from the cylindrical tubular wall, spaced forward of the rearward end and lying in a plane perpendicular to the longitudinal axis of the body . . .", or a "locking structure thereon monolithic with the tubular wall of the syringe" that is "spaced the fixed distance rearward of the ring. . ." all of which is clearly described in Claim 30 of the '261 patent.

Sturges admits that Stolzenberg's invention lacks a ram to move the plunger. However, Sturges again claims that the "old and well known" drive ram technology (that would couple with the plunger face in some fashion) could have "obviously" been derived from Heilman and/or Reilly and combined with Stolzenberg. The Court will not accept Sturges' bare conclusion that utterly lacks a fact-based explanation of how such a combination is "obvious" based on Stolzenberg's osmotic infusion device.

Sturges also asserts that **the Campkin '480** patent discloses or renders obvious each element of the '261 claims. The 1932 Campkin patent discloses the glass hypodermic syringe that may be motor-operated. As noted above with regard to the '669 patent, Sturges ignores the patent's description of a syringe "holder" as an essential element. Campkin does not disclose a "locking structure" that is spaced a "fixed distance" on the syringe itself; rather, the "holder" is separate from the syringe. Sturges also concludes that, if Campkin does not disclose "partial rotation of the syringe in the opening" as the Court

finds it does not, that element is satisfied by Glass and Cochran, thus making that change an "obvious modification" to Campkin.

Sturges does not substantially discuss the Cochran patent, but only mentions it as one of many prior references he considered. (Sturges Declaration ¶45) The Cochran patent (Sturges Exhibit 48) discloses an infusion device consisting of two units, a power module and a syringe, which a patient can attach to the outside of her body, very useful for insulin, chemotherapy, or any longer-term infusion. The patent claims a means to attach the device's two units in order to "irreversibly engage" the connection means of the power module, one embodiment of which is a "plurality of circumferentially-spaced lugs adapted to be non-removably received in bayonet slots of a power module," the flexible lugs provided with ratchet teeth. This "connection means" used in Cochran's infusion device is not "obvious" when applied to a power injector. The infusion device patents discussed, including Cochran, do not reveal the operating pressures under which the devices may perform (and Sturges does not discuss this at all). Sturges' assertion that it would be easy to borrow this feature of Cochran, simply combine it with Campion, and then label it "obvious," is not the clear and convincing evidence needed to establish invalidity of L-F's '261 claims.

Sturges next asserts that **the Michel '439** patent invalidates the '261 claims, either alone or in combination with Glass and

Cochran. (Sturges ¶¶58-59) As noted above, the Michel infusion device has a "connecting part" separate from its syringe, and the patent does not discuss the pressure ranges of the device in operation. Nevertheless, Sturges asserts that each and every claim element is present in the '261 claims. The Court disagrees. Michel does not disclose a "locking structure" on the syringe that is "monolithic with the tubular wall of the syringe." Nor does Sturges explain how or why it would be "obvious" to borrow from Michel's infusion device and apply it to a power injector utilizing a front loading syringe attached with fractional rotation.

Sturges' assertions concerning the rest of the prior art references (Sturges ¶¶60, 61, 62, and 63) are rejected for the same reasons. Sturges essentially borrows elements from disparate inventions, having substantially different structures and purposes, and then concludes that the combination renders L-F's patents invalid. The Court need not accept an expert's conclusion that is unsupported by facts, or by **reasoned** explanation based on skilled learning and knowledge. See also, Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1372 (Fed. Cir. 2000): "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" (internal quotation omitted). The declarations of Solar and Beck are similarly deficient with respect to a lack of reasoned explanation, based on actual patent language and state of the

art, to support their general conclusions on obviousness and anticipation.

The Court finds that L-F's '669 and '261 patents are not invalid on the basis of prior art references, either as anticipated or as obvious. Therefore, L-F's motion for summary judgment for validity of its patents over prior art references (Doc. 437) is **GRANTED**. Medrad's motion for judgment of invalidity based on prior art (Doc. 445) is **DENIED**.

IV. Inequitable Conduct

Finally, L-F has filed a motion seeking summary judgment on Medrad's defense and counterclaim that L-F's patents are unenforceable due to L-F's inequitable conduct before the Patent Office. (Doc. 438) This motion does not deal directly with the claims and the specification of the patents, which the Court has endeavored to address in a comprehensive fashion above. The motion based on inequitable conduct is premised upon the prosecution history of the two patents and their parent, L-F's '031 patent. The Court finds that L-F's motion addressing the alleged inequitable conduct is MOOT due to the Court's rulings set forth above.

SUMMARY OF RULINGS ON L-F'S "FRONT LOAD" PATENTS

For all of the foregoing reasons, the Court grants L-F's motion for infringement (Doc. 436), denies L-F's motion on validity under 35 U.S.C. §112 (Doc. 437), and grants L-F's motion on validity based on prior art (Doc. 450). The Court grants Medrad's motion for invalidity under 35 U.S.C. §112 (Doc. 445),

and denies Medrad's motion for invalidity based on prior art (Doc. 445). The Court finds as moot L-F's motion on alleged inequitable conduct (Doc. 438).

DATED: Oct. 28, 2005

s/Sandra S. Beckwith
Sandra S. Beckwith, Chief Judge
United States District Court